

To: Jacinta.Patel@health.govt.nz

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bcc

Subject: Reclassification Comments

Dear Jacinta,

We note that the comments on the proposed agenda have been today made public prior to the meeting of 66th MCC Meeting Considering Reclassification of Maxigesic Cold & Flu Hot Drink Double Strength. We note that if required, AFT would be available to comment on any specifics during the meeting.

We would appreciate it if, the following points below could be brought to the attention of the Committee

<u>GSK</u> - AFT [sponsor Maxigesic] supports the GSK comments regarding this appeal should be separated from Ibuprofen Sustained Release. Furthermore the comment on the indication in relation to RB does not apply to Maxigesic where the indication is specifically defined.

<u>Pharm Society</u> - AFT would like to comment that it is easier to dissolve a single double strength sachet as opposed to having to tear open and dissolve two lower strength sachets. The potential for confusion is addressed by clear labeling and also in requiring these products to be available only from a Pharmacy i.e. Pharmacy Medicine.

The specific comment on NSAIDs is true but is not directly applicable in that ibuprofen doses of 1200mg or less per day are already widely available to the public with prescription including in grocery. It is noted that this single dose is in fact 300mg which is a relatively low dose and there is a plethora of information that supports the overall safety of low dose ibuprofen.

<u>Pharmacy Guild</u> - There are suggestions around the clarity of labeling which AFT would not oppose as it is in everyone's interests that products are clearly labeled

**RB** - AFT notes that in our view their submission is colored by competitor actions which is particularly highlighted by their suggestion of Ibuprofen 400mg reclassification to suit their application and for our lower 300mg dose application to be more restricted.

<u>AFT</u> would like to draw the committee's attention to the fact that TGA has already approved both Maxigesic Cold & Flu Hot Drink Double Strength and the lower strength as S2 Pharmacy Medicines. Whilst we appreciate that NZ is an independent jurisdiction, it is noted that traditionally Australia is more restrictive in its classification in comparison with New Zealand.

## Your sincerely

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